Docket No. 02N-0276

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

**AMERICAN HERBAL PRODUCTS ASSOCIATION**

ON THE PROPOSED RULE FOR

# REGISTRATION OF FOOD FACILITIES

AS REQUIRED BY

**Section 305**

of the

**Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

April 3, 2003

02N-0276

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The American Herbal Products Association ("AHPA") is the national trade association and voice of the herbal products industry, comprised of companies doing business as growers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs.

**Background and Subject of these Comments**

The United States Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act" or "the Act") to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies, and President Bush signed this legislation into law on June 12, 2002. The Act consists of five separate titles. AHPA and its members have significant interest in the interpretation and implementation of certain of the statutory requirements established in Title III of the Act (Protecting Safety and Security of Food and Drug Supply).

The Food and Drug Administration (FDA) published a notice of proposed rulemaking in the Federal Register on February 3, 2003 to implement two Sections of the Bioterrorism Act, and specifically the requirement for registration of food facilities as required under Section 305 of the Act. This notice specified that comments to the proposed rule should be submitted by April 4, 2003.

Most of AHPA's members are companies that either sell bulk herbs or herbal extracts; that manufacture or process herbal ingredients or consumer goods containing herbs, including dietary supplement and food products; or that market consumer goods containing herbs, including dietary supplement and food products. All such members will be required to register their facilities in accordance with this Section of the Act and will therefore have an interest in the proposed rule. Several of AHPA's members are facilities that will be exempt from registration, such as farms and retailers, and also have an interest in the proposed rule.

AHPA submitted initial comments on August 30, 2002, in response to FDA's express request in correspondence dated July 17, 2002, to identify concerns and provide recommended solutions related to the implementation of Section 305 of the Act.

**Comments to proposed rule**

AHPA has comments related to the following elements of this proposed rule for registration of food facilities under the Act:

1. §1.227(c)(2): The definition proposed for a "facility" includes the term "...under one management at one general physical location..." and the sentence, "A facility may consist of one or more contiguous structures."

   This proposed definition does not address this issue with sufficient clarity. For example, a facility of several structures that were all entered by a common entryway would obviously be contiguous and at one general physical location. Additionally, it can be argued that several buildings or structures that are separated only by being across the street or on adjoining lots on the same street are also contiguous and at one general physical location. But what if several structures under one management are separated by one building or are one block away from each other ?; ...two blocks ?; ...one mile ?; etc. As can be seen, FDA needs to clarify what is meant by "one general physical location."

   AHPA does not believe, however, that the Bioterrorism Act intended to require the owner of a food manufacturer/processor, packer, or holder that conducts its business in two or more structures, whether or not they are at one general location, to file two or more registrations, and suggests that FDA consider revising the definition of a facility to remove any reference to location. The agency may believe that it is important for all relevant structures to be identified, and, while AHPA might agree with this concept, this could be better accomplished by allowing just one registration for firms that use more than one structure and requiring identification of the address of all structures that are under common management on the Facility Registration Form.

   Relative to this issue, FDA has made a statement in the preamble to the proposed rule that differentiates between firms and facilities, stating, "Consistent with the Bioterrorism Act, this proposed regulation's legal requirements apply to facilities, as opposed to firms. A firm is composed of facilities under common ownership." FR 68 at 5389. AHPA notes that the word "firm" does not appear anywhere in the Bioterrorism Act and encourages the agency to take the obvious point that the agency made with this statement – that one firm can own, and therefore manage, multiple facilities – as a jumping off point for simplifying the

registration process for co-owned facilities. There is nothing in the statute that requires or even suggests that registration of a firm's co-owned facilities could not be accomplished with a single registration by the firm. AHPA strongly encourages the agency to consider how it can minimize the burden on such co-owned facilities by specifically allowing a single registration that identifies all facilities.

2. §1.227(c)(3): The Act specifically identifies farms, among other facilities, as exempt from registration. In the definition of "farm" proposed in §1.227(c)(3), the agency has proposed to limit that exemption by defining farms such that all food used in activities related to packing or holding food on a farm would be required to be grown or raised on that farm or be used on that farm; and such that all food used in activities related to manufacturing/processing food on a farm would be required to be consumed on that farm or another farm under the same ownership. The proposed definition for "manufacturing/processing," as given at §1.277(c)(6), includes, "...preparing...food, including food crops [by, for example]...[c]utting,... trimming, washing,...milling, grinding,...labeling, or packaging."

   A number of AHPA's members are growers who operate farms that specialize in growing herbs that are used as ingredients in dietary supplements. All of these farms cut their crops in order to harvest them, and also trim, wash, label and package their raw agricultural products as part of their common agricultural practices. These are activities that most farms engage in. Several of our farm members also mill or grind their harvests in order to meet market demands for raw agricultural products in cut or powdered forms.

   AHPA believes that the proposed definition of "farm" should be modified to include certain of the defined manufacturing/processing activities, whether these are consumed on that farm or one with common ownership or are offered for sale elsewhere, at least insofar as these activities are related to raw agricultural commodities. The specific manufacturing/processing activities that should be allowed on a farm without voiding the statutory exemption to registration granted to farms include at least the following: cutting, at least when this activity is applied to harvest of a farm crop; trimming; washing; labeling, at least when this activity is applied to containers that are not intended for direct consumer purchase; and packaging, at least when this activity is applied to containers that are not intended for direct consumer purchase. The agency should also consider allowing farms to engage in milling and grinding without voiding the statutory exemption to

registration granted to farms, insofar as these activities are common farm activities that most farms engage in.

Another concern related to the proposed definition for "farm" is the inclusion in that definition of the term "one general physical location." Although the word "contiguous" is not included in this proposed definition, the agency does use that word in the preamble to the proposed rule in describing various farm scenarios. FR 68 at 5381.

This proposed definition for "farm" does not address the issue of the location of a farm's cultivated areas with sufficient clarity. For example, a farm that consists of two or more separate cultivated fields separated only by fencing or by a wooded area would obviously be at one general physical location. Additionally, it can be argued that several fields that are separated only by being across the road or across a narrow body of water are also at one general physical location. But what if several fields under the management of one farmer are separated by one other farm or are only a short distance away from each other ?; ...or one mile apart ?; etc.

In addition, it is not uncommon for a farmer to cultivate acreage on property owned by that farmer and also on property owned by others, and to consider the product of all such efforts to be the product of just one farm business. The proposed definition fails to address whether a farm that engages in agriculture on several different properties under separate ownership will be considered a single farm for purposes or registration, in the event that such farm is a "mixed-type facility" as defined in the proposed rule.

AHPA does not believe that the Bioterrorism Act intended to require a farmer that is also a manufacturer/processor, packer, or holder and who farms on two or more separate fields or properties to file two or more registrations, whether or not these are in the same general area. AHPA suggests that FDA consider revising this definition. While the agency may believe that it is important for all relevant properties to be identified, this could be better accomplished by allowing just one registration for farmers that are required to register under the Act and that work more than one field or property, and requiring identification of the physical location of all areas that are under cultivation by that farmer on the Facility Registration Form.

Finally, AHPA includes among its members a number of companies that produce botanical raw material that is not cultivated but is harvested from wild plants. AHPA is aware that FDA has requested comments, in its proposed rule for prior notice of food imports under Section 307 of the Act, whether the term "grower" includes a harvester or collector of wild products including botanicals. FR 68 at 5437. AHPA has provided comments to that question and stated its belief that harvesters or collectors of wild botanicals can be included in the term "grower" as the term is used in the Act, although harvesters or collectors of wild botanicals do not grow botanicals and should be differentiated from growers for certain purposes.

Consistent with the above identified comment to Section 307 of the Act, AHPA requests that an exemption from registration be clearly established in the final rule for individuals and operations that produce some or all of their botanical raw material by harvesting wild plants, either by including such individuals or firms in the definition of a farm or by some other means. These persons do not manufacture/process or pack foods, and they no more hold foods than does a farmer. It must be assumed that Congress did not intend for these individuals or firms to be considered to be facilities for purposes of registration under the Act.

If the agency chooses not to accept this request to clearly exempt producers of wild plants the financial analyses provided in the proposed rule will need to be recalculated. None of the industries identified in Tables 1 or 2 describe individuals or firms that harvest wild plants and so such "facilities" are not included in the number of domestic facilities quantified in Table 9 or in the summary of costs for domestic facilities calculated in Table 10. While no readily available or published information is available to quantify the number of individuals involved in such enterprise in the United States, AHPA has been informed by academics who specialize in the biology of non-timber forest product plants that the best estimates are that there are approximately 100,000 such persons. It can be readily seen that FDA's estimates of the economic impact and effect of this rule are grossly underestimated and are null and void if these individuals are to be treated as facilities for purposes of this registration

3. §1.227(c)(11): The Act specifically identifies "...other retail food establishments," among other facilities, as exempt from registration.

AHPA submitted initial comments on August 30, 2002, in response to FDA's express request in correspondence dated July 17, 2002, to identify concerns and provide recommended solutions related to the implementation of Section 305 of the Act. In these initial comments a potential point of confusion was identified with regard to firms that are retailers by any common definition of that term but who pack food for direct sale to its customers.

AHPA also stated in its initial comments a position that this retailer exemption from registration be clearly defined to include firms that sell food through specific channels of trade, and specifically the channel identified as practitioners and the channel known as "direct-selling" or "multi-level marketing." As stated in the initial comments, several of AHPA's members utilize these channels of trade, and so rely on practitioners such as naturopaths, chiropractors, acupuncturists and others or on individual direct distributors to actually sell and deliver their dietary supplement and food products to the consumer. As a rule these practitioners and distributors do not manufacture, process, or pack any foods, though they do hold these products and in many cases sell these held products to other persons who are not necessarily the end consumer.

The proposed rule has not adequately taken these comments into account and AHPA hereby reiterates its positions in these matters. AHPA appreciates that the proposed definition for "retail facility" clearly includes facilities that not only sell food directly to consumers, but that also manufacture/process food in that facility for direct sale to consumers from that same facility. AHPA believes that the same clarification should be provided in this definition for facilities that pack food in that facility for direct sale to consumers from that same facility.

In addition, although the proposed definition for this term includes some examples of retail facilities that are obviously included in such a definition, such as grocery and convenience stores, it does not include examples of a less obvious nature. AHPA therefore requests the addition of other examples such as "pharmacies that sell foods, including dietary supplements" and "naturopathic or acupuncture clinics that sell herbal dietary ingredients." While the Act plainly intends to exempt all forms of retail food establishments from the requirement to register, the proposed definition is not sufficiently inclusive to assure that there is no confusion related to these less obvious retailers.

Finally, AHPA continues to believe that the Act did not intend for individual persons who sell goods through direct selling channels to register as facilities even though these persons often hold food for sale to an intermediary other than the final consumer. Moreover, it appears as if the agency, in analyzing the economic impacts of implementing the facility registration required by the Act, has assumed that such persons would not be required to register. For example, none of the industries identified in Tables 1 or 2 describe individual direct selling marketers and so such "facilities" are not included in the number of domestic facilities quantified in Table 9 or in the summary of costs for domestic facilities calculated in Table 10. There are estimated to be over 10 million individuals engaged in direct selling in the United States and AHPA has been informed that some individual companies engage as many as 40,000 individual persons to market their dietary supplement products through direct selling channels. It can be readily seen that FDA's estimates of the economic impact and effect of this rule are grossly underestimated and are null and void if these individuals are to be treated as facilities for purposes of this registration. AHPA urges the agency to clarify this issue by clearly stating that such individuals are not facilities for purposes of registration or by exempting these individuals from registration by some other means.

4. §1.231: FDA has proposed to allow registration to be by either electronic or paper/mail means and has stated its intention to devote most of its resources in this area to an electronic system. The proposed rule at §1.231(b) states that registration by mail must be accomplished "[i]f you do not have reasonable access to the Internet...."

   In the initial comments that AHPA submitted on August 30, 2002 strong support was expressed for the use and encouragement of electronic methods for submitting registrations. AHPA continues to support such an emphasis but is concerned that the agency may not provide sufficient resources to assure timely registration of firms who choose to register by paper means.

   This concern stems from statements made in the preamble to this proposed rule in the *Federal Register* of February 3, 2003, and specifically:

   - p. 5380: In describing a paper registration scenario, the agency states that this "...could take several weeks to several months depending on the number of paper registrations."

- p. 5383: "...registration by mail may take several weeks to several months, depending on the efficiency of the mail system and the number of paper registrations that FDA will need to enter manually into the system."

The agency estimates that 71% of domestic facilities and that 31% of foreign manufacturers will register electronically. FR 68 at 5394-5395. Thus, based on the agency's estimates, 29% of domestic facilities and 69% of foreign facilities will register by paper means. It is not acceptable for the registration of such firms to take several weeks to several months. Rather, FDA must plan its resource allocations so that all registrants will be dealt with in a timely manner.

Although AHPA agrees that use of electronic means for registration should be encouraged and will usually be preferred by a firm, AHPA does not believe that a firm should need to show that it does not have reasonable access to the Internet in order to register by mail, as is implied in §1.231(b). AHPA therefore requests that the apparently compulsory language be removed or modified.

AHPA also reads proposed §1.231(b) as unnecessarily exaggerating the tediousness of mail registration, and encourages the agency to remove certain paragraphs in that section that are also relevant to electronic registration, or alternately to include similar paragraphs in §1.231(a), and specifically:

- §1.231(b)(2): Either this paragraph is unnecessary or the following language should be added to §1.231(a): "When you access the form on the Internet, you must fill it out completely and submit it according to the directions provided at the Internet Web site identified in paragraph (a) of this section."
- §1.231(b)(3): Either this paragraph is unnecessary or the following language should be added to §1.231(a): "If any required information on the form is incomplete when submitted, the form will not be accepted for submission."
- §1.231(b)(6): Either this paragraph is unnecessary or the following language should be added to §1.231(a): "If any information you previously submitted is incorrect as entered into the system, you must update your registration as specified in §1.234."

AHPA is aware that the agency has requested comments on how it can encourage use of electronic means for registration. Some obvious ideas include

providing an informative booklet describing how to register online to individuals upon request and to all libraries and other locations that offer Internet access to the public, or to actively encourage libraries to allow individuals to use their facilities to accomplish online registration.

AHPA's initial comments also expressed willingness to work with the agency to organize companies in our trade to serve as reviewers of draft electronic systems. We repeat that willingness here.

5. §1.232(a): The agency has defined specific contact information that will be required to register a facility that goes beyond the information that is specifically identified in the Act. While the Act limits its requirement to "...information necessary to notify the Secretary of the name and address of each facility at which...the registrant conducts business...," FDA's proposed rule would also require identification of additional contact information for the facility, such as a phone number and email address, and would also require the name and address of the parent company, if the facility is a subsidiary of the parent company and emergency contact information for an individual person.

   AHPA does not at this time have any general opposition to the inclusion of the additional information proposed by FDA. However, two concerns have been identified in this section of the proposed rule.

   First, the usefulness of requiring identification of the email address of the facility itself should be reconsidered. Facilities do not always, in and of themselves, have an email address; rather, individuals at the facility have email addresses. Some facilities might be said to have an email address in and of itself but this email address would not necessarily provide communication to the proper contact person for purposes of communication with FDA in regard to facility registration.

   Although AHPA is not a "food facility" for purposes of the proposed rule, AHPA's experience might be enlightening in this matter. The most accurate identification of "AHPA's email" would almost certainly be ahpa@ahpa.org. The recipient at AHPA of emails to that address, however, is an administrative assistant/receptionist who is also the most junior person on the AHPA staff. This is not the person that AHPA would designate for any form of communication with FDA on the matter of facility registration.

In conclusion, AHPA requests that the agency remove the proposed requirement for an email address for the facility itself or make it optional.

The second concern identified in §1.232(a) is its proposed required disclosure of the facility's fax number. This information is not specifically required by the Act and some firms do not currently have fax numbers or may consider removing them if this technology becomes obsolete. The agency should consider identifying this information as "optional" or with the words "if any" or "if available."

6. §1.232(b): The agency has proposed that registrants would be required to identify specific emergency contact information. Although such information is not specifically authorized by the Act, AHPA supports this proposal but suggests that firms be allowed and encouraged to identify alternate emergency contact personnel.

7. §1.232(d): The Act requires identification of "...all trade names under which the facility conducts business...;" similarly, the proposed rule would require each registrant to submit "[a]ll trade names the facility uses."

Although the agency's proposed rule appears to be a straightforward attempt to implement the Act on this matter, AHPA is aware that there is some confusion as to the exact meaning of the term "trade names." Specifically, firms have questioned whether every name under which a firm markets products, even those that are subdivisions of another brand name, are considered to be "trade names" for purposes of the proposed rule; and whether every name for which a firm holds a trademark is considered to be a "trade name."

AHPA is aware that the draft Food Facility Registration Form (Form 3537) includes the parenthetical note, "If this facility uses trade names other than that listed...above, list them below (e.g., 'also doing business as;' 'facility also known as')" at Section 6, i.e., that part of the form wherein trade names are to be recorded. This seems to imply that only the name under which a company does business and none of its brands would be required to be declared. The following discussion may therefore be unnecessary except for the purpose of requesting that the agency make the implication of this parenthetical note absolutely clear in the final rule.

A hypothetical situation may assist in understanding this identified concern. A company called AAA Herb Company, doing business under that name, sells their

products as "Triple-A Brand® Herbs." They sell 2 products: a soy product, sold as "Oh-So-Soy® by Triple-A Brand® Herbs" and a cherry bark product sold as "So-Very-Cherry® by Triple-A Brand® Herbs." All of their product labels state "Manufactured by (or for) AAA Herb Company, [name of city, state, zip]."

The parenthetical statement on draft Form 3537 referred to above seems to imply that, in the example above, Section 6 would be left blank as the company does not "also do business as" any other name, nor is the "facility also known as" any other name. If this is an accurate understanding of this part of the proposed rule, the term "trade names under which the facility conducts business" is synonymous with and has no meanings different from "names under which the facility conducts business." Given that current federal labeling regulations already require that the manufacturer, packer, or distributor must be identified on the label of all food products, AHPA believes that this most narrow meaning of this term is sufficient on a facility registration. If this is an accurate understanding of this part of the proposed rule the identification of what are commonly called "brands" ("Triple-A Brand® Herbs") would not be required. AHPA requests that the agency clarify its position on this point.

In addition, AHPA believes that the Congressional intention in requiring disclosure of "trade names" can be satisfied without identifying all of the trademarked and/or stylized names that a firm uses to identify any of its products. AHPA also requests that the agency clarify its position on this point.

Another area of confusion with regard to registration of trade names has also been identified. AHPA includes among its members a number of companies that serve as contract manufacturers and do not market any consumer goods themselves, nor does their name appear as the manufacturer on any packaged consumer goods. In fact, some such firms may not know the brands under which their manufactured/processed goods are sold as their customers receive these goods in bulk form for packaging under several brand names. To further complicate this issue, a company that markets but does not manufacture a product might purchase the product from one contactor for one lot and another contractor for the next lot (note that this practice is not limited to dietary supplements but is also common in the food trade, for example in the area of "generic" or store brands).

It is AHPA's position that the only name(s) that should be considered by a contract manufacturer to be a "trade name under which the registrant conducts business" is the name(s) under which their contract manufacturing is conducted, and should specifically exclude the brands and names of their client's products. AHPA again requests that the agency clarify this matter. AHPA strongly suggests that the agency recognize that the best way to identify a manufacturer/processor that works on a contractual basis and does not actually market finished goods will be by contacting the marketer of the finished goods, that is, the company whose name is on the package.

In addition, AHPA is aware that there are other firms, such as distributors who serve as middlemen between a manufacturer and a retailer, i.e., they hold goods but do not manufacture/process or pack goods, who similarly should not be required to list all of the brands that they sell as "trade names under which the registrant conducts business." AHPA requests that the agency clarify this point, and again suggests that the agency recognize that the facility that needs to be contacted about a finished product is the company whose name is on the finished product package.

In summary, AHPA requests that a definition for "trade names" be provided in §1.227 that addresses the above identified issues, or suggest alternate means to address and clarify these, such as a clear discussion in the preamble to the final rule or clear examples in the final rule.

8. §1.232(e): The Act authorized but did not require identification of "the general food category (as identified under Section 170.3 of title 21, Code of Federal Regulations) of any food manufactured, processed, packed or held at such facility."

FDA has proposed that registrants would, in fact, be required to provide information as to categories identified under 21 CFR §170.3 for the registrant's foods, but only if there is currently a defined category in §170.3. Thus, for dietary ingredients and dietary supplements, some products, and specifically those that are proteins, amino acids, fats and lipid substances, vitamins, or minerals would require identification as FDA has opined that these fit the definition of §170.3(o)(20); while other dietary ingredients and dietary supplements that are animal by-products and extracts or herbals and botanicals would not be required to provide this information but could optionally do so.

In preliminary comments filed on August 30, 2002, AHPA noted that dietary supplements are not included in the 43 general food categories that are defined in 21 CFR 170.3(n) and that it would be useful to AHPA members to be able to identify their products in one or another category if the Secretary does determine that this information be required for registration of a food facility.

FDA has provided a rationale as to why information about the general food category should be included in a registration and AHPA does not oppose the inclusion of such information. AHPA does not believe, however, that the proposal offered by FDA in this regard, which would have the effect of splitting the dietary supplement category into required and optional subsections, is appropriate. To begin with, although the Act does not limit this discussion to the single subparagraph §170.3(n), the plain language of the Act should be read to imply exactly such limitation. The Act authorizes but does not require the Secretary to require identification of "...the **general food category** (as identified under Section 170.3 of title 21, Code of Federal Regulations)..." of the registrant's foods (emphasis added). Only one subparagraph – §170.3(n) – is identified as consisting of "general food categories." To drift into §170.3(o), which describes "physical or technical functional effects" rather than food categories, is beyond the agency's authority under the Act as §170.3(o) does not identify any "general food categories."

AHPA strongly suggests that the agency use the vehicle of this proposed rule to add an additional food category under §170.3(n) for dietary supplements rather than subjecting the dietary supplement to a needless and irrational process, as would be the case under the current proposed rule. The agency has clear authority to establish regulations for the efficient enforcement of its mission and should not conclude that the Congressional intention was to limit the agency to categories in §170.3(n) that existed on the day that the Act was signed into law.

9. §1.232(g): The certification statement proposed in this subparagraph is inadequate to ensure either the veracity of the information provided or, more importantly, the identity and authority of the person submitting it. The regulation includes no protections that would prevent intentional or unintentional abuse of the system, to the potential detriment of both national security and of legitimate businesses. Without some effective means of verifying at least the identity and authority of the person submitting the registration, the proposed system will be

easily subject to misuse and mischief. AHPA encourages the agency to address this shortfall.

10. §1.243(a): The Act specifies that certain information required to be provided by food facilities will not be subject to disclosure under 5 U.S.C. §552 and the proposed rule would implement this protection. The Act states in newly added section 415(a)(4) of the Federal Food, Drug and Cosmetic Act (FFDCA), "...any registration documents submitted pursuant to this subsection shall not be subject to disclosure under section 552 of title 5, United States Code," and also states, "Information derived from...registration documents shall not be subject to disclosure under section 552 of title 5, United States Code, to the extent that it discloses the identity or location of a specific registered person."

    In implementing this Section of the Act the proposed rule closely mirrors the language of the Act. AHPA is concerned, however, that the protection from disclosure specified by the Act and proposed by FDA is too narrow. Further, although the plain language of the Act specifically identifies protected information to just the actual registration forms and information related to identity or location of a specific registered person, AHPA does not believe that the Act forbids FDA from expanding this protection, and AHPA requests that the agency consider expanding this protection to all information derived from registration documents that has not been previously disclosed to the public.

    Examples of the kind of information that might be required in registration that is not related to identity or location of a specified registered person but that a firm might wish to protect includes, among other things, a preferred mailing address, if any; a parent company name, if any; seasonal dates of operation, if any; and the establishment type or types.

    An additional example of such information is related to the discussion above in #7 of these comments, and specifically to contract manufacturers. AHPA has suggested that the brands manufactured/processed by such firms on behalf of their clients should not be considered to be trade names under which these contact manufacturers do business, and thus would not be required to be disclosed in registration documents. It is possible, however, that FDA will not accept this suggestion. If the agency does, in fact, require this information to be included in the registration of such facilities, it must be protected from disclosure. The association between the contract manufacturer and their client who markets

the product is considered to be confidential business information that must be protected from disclosure under the Freedom of Information Act.

There is another matter related to protection from disclosure of information that is also of concern to AHPA. The Act requires the Secretary to "...compile and maintain an up-to-date list of facilities that are registered..." under this Section of the Act and provides the same protection from disclosure of this list. The proposed rule, however, is silent on this additional protection. AHPA requests that the final rule specifically acknowledge that the statutory requirement for compilation and maintenance of the above described list will be met; that the protection from disclosure granted by the Act be clearly established; and that the procedures by which submitters may obtain this protection from disclosure be clearly described within the regulation.

**Responses to FDA's specific requests for comments**

In numerous places throughout the preamble to the proposed rule FDA requested comments. AHPA is not submitting comments to the majority of these requests at this time and takes no position on any of the issues on which no comment is provided. AHPA does, however, offer the following comments to specific identified questions.

Filing of updates. The agency has proposed in §1.234 to require that an update be filed within 30 days of the change in any of the information included in a registration.

The agency asked for comments on this 30-day timeframe. AHPA believes 30 days to be a reasonable timeframe for this requirement. The agency also asked for comments on how the proposed requirement for updates even when the only change in information is related to that information which was optional in the original registration might affect the submission of optional information. AHPA does not pretend to be expert in evaluating this question, but common sense suggests that such a requirement would be a disincentive to providing optional information at the time of the initial registration.

Duplication of information. The agency has stated its intention to minimize the burden of this rule and the submission of duplicative information, and requested comments on whether there are registration requirements under which facilities must submit duplicative information to more than one Federal agency and whether there is any way to minimize such duplication, among other related requests.

AHPA does not at this time have any comment to offer to the specific request for comments identified here, in that AHPA understands these questions to have been posed specific to Federal inter-agency duplication. However, AHPA does believe that, when a food facility is required to register with FDA under the Bioterrorism Act and is also required to register with FDA for some other purpose, FDA should combine these facility registrations into a single registration process. For example, some firms that manufacture dietary supplements also manufacture acidified food or low-acid canned food or drugs, which are facilities that are also required to register with FDA. The agency should work to organize these separate registrations to accomplish multiple purposes, for example by allowing such firms to submit optional attachment to one registration or another.

In addition, in initial comments filed on August 30, 2002, AHPA identified its awareness that several states require registration of facilities where food is manufactured, processed, packed or held. AHPA suggested that it is possible, or even likely, that the information included in the Federal and state registrations will contain some redundancies and suggested that the rules for registration with FDA take into account, to the degree possible under the Act, the registration requirements of the several states. AHPA proposed, for example, that FDA might consider providing options in the registration process that allow a facility to authorize information in the registration to be forwarded to those states that presently require registration. AHPA repeats these suggestions here.

Use of FDA's product code builder. The agency has stated its intention to use the categories defined in FDA's product code builder as the main categories of foods on the registration form with categories from §170.3 organized below these headings. FDA provides as part of its rationale for organization information according to FDA's product code builder the need to "address industry's concern that the food product categories in §170.3 are unworkable." The agency has solicited comments as to whether this proposal addresses concerns received in earlier comments and also satisfies its obligations under the Act.

AHPA provided initial comments that described concerns related to the use of categories under §170.3, as is discussed in comment #8 above. FDA's proposal to use its product code builder in the manner proposed does not in any way address these concerns. Further, AHPA believes that the FDA food products categories are unworkable insofar as this system addresses dietary supplements, and has provided

an in depth discussion of this matter in comments filed on this date to Docket No. 02N-0278 related to prior notice of imported food shipments. Comments provided in Docket No. 02N-0278 on FDA's product code builder should be considered to be simultaneously submitted to the docket that is the subject of the present comments.

Revocation of registration. The agency requested comments on circumstances under which a registration should be considered null and void or be revoked.

AHPA believes that, at a minimum, registration should be considered null and void if it is demonstrated that the registration was submitted fraudulently or by an unauthorized party. Other circumstances for voiding the registration also exist and are addressed in other provisions of the FFDCA.

Estimation of number of updates. FDA estimates that 20 percent of all facilities will be required to update their registrations each year and requests comments on this assumption.

According to the proposed rule, an update to a registration will be required within 30 days of any change in information included in a registration, whether that information was required or provided even though optional. The agency's rationale for its estimate that 20 percent of facilities will be required to file an update in any given year is apparently provided in a single statement in the preamble to the proposed rule, which states, "...given that 10 percent of facilities go out of business each year, FDA estimates that a higher percentage, 20 percent, of all facilities will have to update their registration each year."

AHPA sees no rational relationship between the fact that 10 percent of facilities go out of business each year and any estimation of the number of facilities in which any of the information provided in their registration changes in any given year. AHPA does not, however, have an alternative estimate to offer, but encourages the agency to consider information about how often facilities relocate, or change their preferred mailing address, or change their ownership such that the parent company changes, or change their management such that the emergency contact changes, etc. Of particular significance and related to comment #7 above, if the agency defines "trade name" broadly, updates to registration could conceivably be an almost monthly process for firms that are contact manufacturers or distributors. AHPA encourages the agency to take all of these factors into account in estimating the prevalence of registration updates.

Effect on small entities. The agency has requested comments on the effect of the proposed rule on small entities and on whether it would be consistent with the Act to set staggered compliance dates to give small entities more time to comply.

AHPA does not believe that the initial registration of small food facilities, as envisioned by the Act, will place a significant burden on small entities so long as FDA implements the registration requirement in a reasonable and efficient manner and in a manner that takes into account the comments provided here. AHPA does not believe that a staggered compliance scheme is needed.

**Additional comments**

FDA should provide a mechanism whereby an accurate printed record can be produced of electronically submitted registration information, including the exact date and time of submission and the Internet protocol (IP) address from which the submission was made. The agency may want to require both the agency itself and registrants to keep such a copy in their records. Such a paper copy would be useful for review in order to confirm that the submitted information is correct, e.g. by the company's management personnel other than the person submitting the form; for review by the company's administrative or management personnel in order to determine whether revisions are necessary as the company's operations change; in case of investigations into possible fraud, e.g. the submission of information by someone other than the party authorized by the company; and for review by FDA or (where authorized) state inspectors during facility inspections, to confirm that the submitted information is accurate and complete.

Another issue of interest and concern to AHPA's members is the statutory implementation date for food facility registration, and specifically that their businesses will suffer through no fault of their own if the agency fails to complete all that is necessary by December. While AHPA assumes that FDA will diligently work to meet this deadline any uncertainty in this matter should be communicated promptly and openly so that the Congress can consider appropriate actions.

AHPA appreciates the opportunity to provide these comments to the proposed rules for registration of food facilities under the Bioterrorism Act and hopes that the agency will treat these comments seriously.

Respectfully submitted,

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